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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,172	03/21/2007	Hirotoshi Adachi	MUR-047-USA-PCT	4754

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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06/22/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,172	ADACHI ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 13-23* is/are pending in the application.

4a) Of the above claim(s) *4-8, 15, 16, 19, 20, 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9,13,14,17,18,21 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 03/29/2011.

Claims 1-23 are previously presented.

Claims 9-12 are currently canceled.

Claims 1-8, and 13-23 are pending.

This application contains claims 4-8, 15, 16, 19, 20, and 22 drawn to an invention nonelected with traverse in the reply filed on 10/28/2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-3, 9, 13, 14, 17, 18, 21, 23 are included in the prosecution.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-3, 9, 13, 14, 17-18, 21, 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 12/087,055. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: transdermal device comprising holder (reads on the diaphragm) having a hole and drug loaded member on one side and container comprising dissolution liquid on the other side. The present claims anticipate the copending claims that are later filed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-3, 9, 13, 14, 17-18, 21, 23 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,883,504. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed and covered in the issued patent since the referenced copending applications and the instant application are claiming common subject matter as follows: transdermal device comprising holder (reads on the diaphragm) having a

hole and drug loaded member on one side and container comprising dissolution liquid on the other side. The present claims anticipate the issued claims that are later filed.

Response to Arguments

4. Applicant's arguments filed 03/29/2011 have been fully considered but they are not persuasive.

The examiner notes that the application 12/441,842 is now matured to patent 7,883,504. Applicants argue that none of the copending application or the issued patent covers the structure currently claimed. In response to this argument, it is argued that the present claims are earlier filed, and they anticipate the copending claims and the issued patent. The present claims are species of the claims of the copending application and the claims of the issued patent, and species anticipates the genus.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-3, 9, 13, 14, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Heiber et el. (US 4,917,676), Wakizaka et al. (JP 09-124468), and Konno et al. (US 4,842,577), all references are of record.

Applicant Claims

Applicant s' claim 1 is directed to a patch activated in use comprising: an absorber containing a dry drug and formed of a material capable of absorbing a liquid; a wall material arranged around the absorber and having an adhesive layer on the lower surface thereof; a support arranged on the absorber and the wall material and having an opening at the center; a diaphragm arranged on the support; and a dissolution liquid

reservoir arranged on the diaphragm, holding a dissolution liquid dissolving the drug in a space with the diaphragm, and having a protruding portion which breaks the diaphragm by pressure, wherein the dissolution liquid reservoir is formed by subjecting a sheet material to mold processing, having the protruding portion processed to at least a portion, and wherein a portion of the diaphragm in contact with the dissolution liquid has an oval shape and the protruding portion of the dissolution liquid reservoir has a linear top end portion extending along the longitudinal axis of the oval, and when the length of the linear top end portion is represented by L1 and the length of the longitudinal axis of the portion of the diaphragm in contact with the dissolution liquid is represented by L2, the following relationship is satisfied $0.1\times L2 \leq L1 \leq 0.5\times L2$, or wherein a portion of the diaphragm in contact with the dissolution liquid has a circular shape and the protruding portion of the dissolution liquid reservoir has a cruciform top end portion, and when the length of both bars of the cruciform top end portion are represented by L10 and L11, respectively, and the diameter of the portion of the diaphragm in contact with the dissolution liquid is represented by L2, the following relationship is satisfied $0.1\times L2 \leq L10 \leq 0.5\times L2$ and/or $0.1xL2 \leq L11 \leq 0.5xL2$.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Heiber teaches transdermal drug delivery device in pre-activated state for storage stability, manufacture safety and user safety, which is activated by the user before use or after application to the skin (abstract). The device comprises two

reservoirs 2 and 3 on top of each other, one contains an activating substance and one contains therapeutic agent and separated by non-permeable membrane 10 that may contain a depth slit to weaken the membrane. Membrane 10 is brustable by pressure (col.3, lines 51-53; col.4, lines 41-65; col.5, lines 8-15; figure 3; claims). Once the activating agent brought into contact with the therapeutic agent, the device is activated and drug flow from the reservoir to the skin begins (col.6, lines 10-17). Activating agent can be solvent or solutions to elute the drug (col.7, lines 7-15).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

While Heiber teaches transdermal device activated in use by bringing a therapeutic agent and activating agent in contact by rupturing a separating membrane, however, the reference does not explicitly absorbent material containing the therapeutic agent located under the separating membrane as instantly claimed by claim 1.

While Heiber teaches rupturing the membrane separating the activating substance and therapeutic agent to activate the device, and teaches separating membrane weakened by a slit, however the reference does not explicitly teach protrusion to break the membrane, or the separating layer having opening in the center as claimed by claim 1 or the separating membrane is made of aluminum foil as claimed by claim 23.

Wakizaka teaches transdermal device that hardly deteriorates or inactivate medicine during storage, the device comprises blister enclosing and sealing liquid

medicine and film sealing the blister and its under surface. The blister comprising protrusion protruding into its interior (abstract, drawings; paragraph 0004). The medicine can be impregnated into absorbent material (paragraph 0017). The device comprises drug transmission layer 2 on the lower surface of the blister and separated from layer 2 by easily destroyed coating membrane 5 of aluminum foil representing the diaphragm layer (paragraphs 0014, 0024). The device has exfoliation layer 4 (release liner) and adhesive to stick the device to the skin (paragraphs 0005, 0009, 0024). The drug transmission layer is drug absorbent material (paragraph 0015). Figures show that the drug absorbent layers are surrounded by wall that has adhesive on the lower surface. The reference teaches that during use, pressure is applied to the top of the protrusion to destroy the drug coating membrane (paragraphs 0007, 0024).

Konno teaches a transdermal drug device comprising a drug-loaded member (1) provided on the side facing skin of the device, a dissolution liquid-storing container (6) provided on the other side of the device away from the skin, and thin aluminum foil film separating the dissolution liquid-storing container (6) and drug-loaded member (1), wherein the aluminum foil separating membrane comprising liquid passing hole (Figure 4; col.2, line 37 to col.5, line 21). The dissolution liquid passing hole allows for passage of the liquid from the dissolution liquid-storing container (6) into the drug-loaded member (1). As shown in Figure 4, the dissolution liquid-storing container (6) has a recessed portion for storing liquid and a projected portion disposed in the recessed portion, the projected portion being opposed to the dissolution liquid passing hole. The projected portion has a tip for rupturing the thin aluminum foil membrane. The

medicament containing layer is absorbent layer impregnated with the drug (col.2, lines 65-68). The device is excellent in skin safety and provides efficient absorption of medicament to the skin (col.1, lines 63-65; col.5, lines 5-8).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device activated in use by bringing a therapeutic agent and activating agent in contact by rupturing a separating membrane as taught by Heiber, and use the structure of the device taught by Wakizaka and Konno that encloses the activating agent in blister comprising protrusion and impregnates the therapeutic agent in an absorbent material wherein the protrusion ruptures the separating membrane upon applying pressure, and use aluminum foil as separating membrane and use a layer that surrounds the drug containing layer secured to the skin by adhesive. One would have been motivated to do so because Wakizaka teaches that such a structure of the device hardly deteriorates or inactivates medicine during storage and aluminum foil is easily destroyed by pressure and because Konno teaches such a device is excellent in skin safety and provides efficient absorption of medicament to the skin. One would reasonably expect formulating transdermal device comprising blister containing an activating agent and protrusion and a therapeutic agent impregnated into absorbent material wherein the blister and the therapeutic agent are separated by easily destroyed aluminum foil layer by virtue of applying pressure to the protrusion, wherein

the device is stable during storage and activated in use and has excellent in skin safety and provides efficient absorption of medicament to the skin.

Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising blister containing an activating agent and protrusion and a therapeutic agent impregnated into absorbent material wherein the blister and the therapeutic agent are separated by easily destroyed aluminum foil as taught by combination of Heiber, Wakizaka and Konno, and make a whole in the aluminum foil membrane as taught by Konno. One would have been motivated to do so because Heiber desired to weaken the membrane separating the two compartments by slit and because Wakizaka desired to rupture the separating membrane, and because Konno teaches that presence of a whole in the separating membrane will provide easy rupturing area to facilitates the passage of material and communication between the two compartments. One would reasonably expect formulating transdermal comprising blister on the side of the device away from the skin containing an activating agent and protrusion, and a therapeutic agent impregnated into absorbent material on the skin side of the device wherein the blister content and the therapeutic agent are separated by easily destroyed aluminum foil having a hole and rupture by applying pressure to the protrusion, wherein the device is stable during storage and easily and effectively activated in use to efficiently and safely deliver the therapeutic agent to the user.

Regarding the limitation of the dissolution reservoir is formed by subjecting a sheet material to mold processing….., this limitation is directed to method of making a

device that does not impart patentability to product claims, and product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe,* 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985), wherein the product-by-process claim was rejected because the end product, in both the prior art and the claimed product were the same. The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). Since the claimed product appears to be substantially identical to that of the prior art, the burden is shifted to applicant to show an unobvious difference between the claimed product and the prior art product and to come forward with evidence establishing an unobvious difference. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974); *In re Marosi,* 710 F.2d 798, 802, 218 USPQ 289, 292

(Fed. Cir.1983); *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). It has been held that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Regarding the structure limitations currently added to claim 1, the combination of the references teaches the present structure of the claimed device as a whole, and therefore the device drawn from combination of the references will display and satisfy the claimed equations and relationships as claimed by claim 1.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

9. Claims 17, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Heiber, Wakizaka and Konno as applied to claims 1-3, 9-14 and 23 above and further in view of Blum et al. (US 7,337,593), all references are of record.

Applicant Claims

Applicant s' claims 17 is directed to method of making the reservoir by molding a sheet, and claim 18 recites the thickness of the sheet and claim 21 recites the material of the sheet to include fluorocarbon resin film.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The combined teachings of Heiber, Wakizaka and Konno are previously discussed in this office action.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

The references however do not teach method of making the reservoir by molding a sheet as claimed by claim 17, the thickness of the sheet as claimed by claim 18, or the material of the sheet as claimed by claim 21.

Blum teaches blister suitable for packaging pharmaceuticals that has improved excellent moisture and vapor barrier effect including fluorocarbon resin film (title and abstract; col.2, lines 42-48; col.3, lines 1-2; col.8, lines 52-56). Fluorocarbon polymers are molded to form shaped blister film covering (col.6, lines 7-11). The film having thickness from 1.3-2540 μm to provide readily flexible film (col.8, lines 57-65).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal comprising blister containing an activating agent and protrusion, and a therapeutic agent impregnated into absorbent material wherein the blister and the therapeutic agent are separated by aluminum foil layer as taught by the combination of Heiber, Wakizaka and Konno, and further form the blister by molding a fluorocarbon resin film having moisture barrier property and having thickness from 1.3-2540 μm as taught by Blum. One would have been motivated to do so because Blum teaches that molded fluorocarbon resin film having thickness from 1.3-2540 μm is excellent moisture and vapor barrier and further readily flexible. One would reasonably expect formulating the wall of the blister of the device taught by the combination of Heiber, Wakizaka and Konno by molding fluorocarbon resin film having thickness from 1.3-2540 wherein the blister wall is excellent barrier and flexible so that suitable for pressing the protrusion inside the blister and mean while protect the enclosed material from moisture and vapor.

Regarding the claimed water vapor permeability as claimed by claim 17, Blum teaches excellent moisture and vapor barrier property of fluorocarbon resin film which provides low permeability which reads on the claimed values.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

10. Applicant's arguments filed 03/29/2011 have been fully considered but they are not persuasive.

Applicants argue that none of the references teach the newly added limitations. Neither of the examiner's secondary references of Wakizaka and Konno cures the deficiencies of the primary reference, Heiber. One of the advantages of the structure shown in Fig. 9 is that when the protruding portion 93 is pressed in use and the diaphragm 92 is broken along the linear top end portion, solution 91 flows out well with the result that the remaining amount of solution can be reduced. An advantage of this structure is that when the protruding portion 103 is pressed in use and the diaphragm 102 is broken widely by the cruciform top end portion 104, the solution can flow out well, with the result that the remaining amount of solution can be reduced.

In response to this argument it is argued that the secondary references teach the protruding portion as instantly claimed. The combination of the prior art teaches transdermal device comprising blister on the side of the device away from the skin containing an activating agent and protrusion, and a therapeutic agent impregnated into absorbent material on the skin side of the device wherein the blister content and the therapeutic agent are separated by easily destroyed aluminum foil having a hole and rupture by applying pressure to the protrusion. Since the references suggest all the components of the instant claims, the properties and advantages of the instant product would be an intrinsic property. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 596 F.2d 1019,

201 USPQ 658 (CCPA 1979). If the prior art meets the structure recited, the properties must be met or Applicant's claim is incomplete. This is in line with *In re Spada*, 15 USPQ 2d 1655 (1990) which holds that products of identical chemical composition cannot have mutually exclusive properties.

Regarding satisfaction of specific relationship between L1 and L2 or L10 and L11 as instantly claimed by claim 1, such relation is expected to be displayed by the device taught by the prior art having the same structure and materials as instantly claimed. Further, determination of such a relationship it is not part of the claimed transdermal device. It is only an in-vitro relation that is expected to be the same for two similar delivery devices tested under the same circumstances, and the recitation of this in-vitro tested relation does not impart patentability to claims directed to transdermal device. The burden is on applicants to show that the claimed testing process resulted in novel and unobvious difference between the claimed product and prior art product since the Patent Office does not have the facilities for preparing the claimed materials and comparing them with the prior art inventions. See *In re Best*, 562 F.2 1252, 195 USPQ 430 (CCPA 1977); and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

In addition, regarding applicant's arguments of advantages of the present device in the instant specification, it is the examiner's position that these advantages are not unexpected and therefore cannot rebut prima facie obviousness. The examiner directs applicant's attention to MPEP 716.02 (a). "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness of the claims at

issue." *In re Corkhill*, 711 F.2d 1496, 266 USPQ 1006 (Fed.Cir. 1985). *In Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. Furthermore, the MPEP states, "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon,* 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967).

It has been decided by the court that: “When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious,” the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.”

In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR

INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007). A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Communications

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571)272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG